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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,383	CHE ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☒ Claim(s) *4-8 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 11-24 are pending and the subject of this Office Action.

Claim Objections

Claims 4-8 and 19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim depends from another multiple dependent claim, claim 3. See MPEP § 608.01(n). Appropriate action is required.

Claim Rejections - 35 U.S.C. §§ 101 and 112.2

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

First Rejection

Claims 20-21 and 24 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claims 20-21 and 24 provide for the use of amorphous atorvastatin calcium, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to

encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20-21 and 24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Second Rejection

Claim1 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. The term "atorvastatin lactone of formula II" in claim 1 is a relative term which renders the claim indefinite. The term "atorvastatin lactone of formula II" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. To overcome this rejection, Applicants should consider amending claim 1 to incorporate the chemical structure for atorvastatin lactone of formula II.

Claim 2 recites the limitation "residual amounts of solvent other than water." There is insufficient antecedent basis for this limitation in the claim, because water is the only solvent of claim 1 and thus, claim 2 fails to further limit claim 1.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,087,511 [hereinafter referred to as "Lin et al"](the reference is being considered in its totality)[1].

Lin et al disclose a novel process for making amorphous atorvastatin hemi calcium salt, noting that the same is useful as an inhibitor of HMG-CoA and therefore, useful in the treatment of hypercholesterolemia (Col. 1, lines 13-21). The disclosed process comprises a beginning with a mixture comprising atorvastatin lactone and methanol reacted with an aqueous solution of sodium hydroxide to form an open-ring sodium salt. The organic layer is discarded and the aqueous layer is extracted with MTBE. When the organic layer is again discarded, the aqueous solution of the sodium salt is heated and to the solution added calcium acetate hemihydrate dissolved in water. Shortly thereafter, the mixture is seeded with a slurry of crystalline atorvastatin. Some time thereafter, the mixture is heated, then cooled, filtered, and wished with a solution of water and methanol followed by water. The resulting atorvastatin solid is dried under a vacuum to give the crystalline form, and through a process disclosed in Example 2, the crystalline form because amorphous atorvastatin (Col. 5, lines 11-65)..

[1] Lin et al is cited on Applicants' IDS.

The adjustment of particular conventional working conditions such as quantity of seeds of amorphous atorvastatin calcium relative to the weight percent of atorvastatin lactone and the stoichiometry of sodium hydroxide relative to the same, and the timing of the hydrolysis reaction are mere matters of routine optimization and judicious selection well within the purview of one of ordinary skill in the art.

One of ordinary skill in the art would have been motivated to perform the instant invention based on the disclosures in Lin et al because as noted therein, although amorphous atorvastatin solids were known to exist in advance of the advent of crystalline atorvastatin, "the production of amorphous atorvastatin by the previously disclosed processes was not consistently reproducible (Col. 1, lines 61-65). Further, it was also known that the bioavailability patterns of drugs often differ based on whether their forms are amorphous or crystalline, for example, making it desirable to have a procedure for converting the crystalline form to the amorphous form (Col. 2, lines 1-7).

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare amorphous atorvastatin calcium by the hydrolysis of atorvastatin lactone to form atorvastatin sodium salt, to suspend the same into a solution of aqueous calcium acetate, and then, to isolate and dry the same to form amorphous atorvastatin calcium salt and that the same would be effective in the treatment of hypercholesterolemia.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

04 February 2008

Alicia Hughes
Art Unit 1614

RAYMOND HENLEY III
PRIMARY EXAMINER
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